AMERICAN FEED INDUSTRY ASSOCIATION

December 19, 2005

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

VIA ELECTRONIC MAIL

Re: **Docket No. 2002N-0273, Proposed Rule Substances Prohibited From Use in Animal Food or Feed**

Dear Sir/Madam:

The American Feed Industry Association (AFIA) is the national trade association representing feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers and other firms which supply goods and services to the feed industry. AFIA's nearly 600 corporate members manufacture more than 75% of the nation's primary feed. In addition, AFIA's membership includes 21 state and eight national trade associations representing feed manufacturers and ingredient suppliers. Many AFIA members are subject to the current BSE feed regulation (21 CFR § 589.2000), and AFIA offers these comments on their behalf.

AFIA believes there is no FDA regulation with a higher level of industry compliance than this BSE feed rule, and applauds the agency's continuing industry education and compliance efforts. Continuing programs to promote education about, compliance with, surveillance for and enforcement of this rule are essential to insuring BSE does not establish and amplify in the U.S., as well as for maintaining high level of confidence in the U.S. beef supply by consumers and global trading partners.

AFIA renews its commitment to support FDA's efforts, and to seek adequate funding for continued education and compliance efforts at the state and federal levels. Only through this cooperative industry-government effort can we be effective in assuring the consuming public and our trading partners of the safety of the U.S. beef supply, while insuring continued animal health.

AFIA Supports FDA's Proposed Rulemaking; But Believes One Change is Needed

AFIA generally supports the proposed changes to the BSE feed rule (21 CFR §589.2000) and creation of a new subsection 21 CFR § 589.2001. The approach proposed significantly reduces the already very low risk of BSE in the U.S. and is less costly than the approach proposed by FDA in January 2004.

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However, AFIA remains very concerned about the costs of carcass disposal from animals excluded from this proposed rule, as well as carcasses and materials that must be disposed of due to the consequences of this rule, i.e. significant changes in the rendering industry brought on by the proposed brain/spinal cord (B/SC) exclusions, including B/SC from all dead and nonambulatory animals regardless of age to be legal for rendering and feeding.

AFIA agrees with FDA's proposal to remove from the entire feed supply chain a limited list of certain tissues from cattle to prevent the inadvertent commingling of prohibited mammalian protein with ruminant feed. The rationale FDA puts forward for making this proposal is scientifically defensible -- with one exception.

AFIA urges the agency to reduce the potential amount of unrenderable product that will likely result from the exclusion of SRMs and nonambulatory and dead animals for which B/SC is impractical or impossible. We believe the agency is being inconsistent in its application of risk reduction science by proposing to require the removal of B/SC in all dead or nonambulatory cattle, while allowing the feed use of B/SC from cattle less than 30 months of age for cattle which have been inspected and slaughtered.

AFIA asserts the even-handed application of science dictates the retention of the B/SC in the feed chain from cattle less than 30 months of age provided the age of the animal can be verified. This approach is consistent with the generally accepted principle that cattle under 30 months of age have been rarely, if ever, diagnosed with BSE. This position, however, is dependent on a verifiable method of determining age. For dairy operations, we believe herd records would justify that requirement. Feedlot calves would also clearly meet this requirement. Amending this portion of the proposal will further reduce the expected amount of material to be disposed of with no expected risk elevation. The cost savings would be significant and is detailed in comments by the National Renderers Association.

A Federal Government Task Force Should be Developed to Address Carcass Disposal

AFIA's primary concern, however, is the lack of a coordinated federal program -- or even guidance to industry for carcass and SRM disposal resulting from this proposal. FDA can reduce a significant amount of this material by amending the proposal to adopt AFIA's suggestion allowing use in non-ruminant feed of B/SC from dead and nonambulatory cattle less than 30 months of age.

At the same time, AFIA strongly urges the federal government to form a high-level state-federal task force to address the disposal issue. At the very least, this task force should include veterinary public health officials from each state. The task force should develop disposal options, and identify funding mechanisms to effect these options. The affected industries would be pleased to host roundtables, technical conferences or other meetings to address this issue.

The failure of the federal government to address responsible and environmentally responsible disposal of the increased amount of cattle material and animals requiring options

may lead to potential zoonootic disease transmission and further possibility of contamination of soil and water. AFIA believes FDA should promulgate a rule with the least amount of disposal issues and the maximum amount of risk reduction and the Federal Government agencies responsible for these issues should begin work when or if FDA finalizes this rule.

Lack of a B/SC Test Method is a Concern, as Well as FDA's Potential for Using PCR

FDA raises the issue of a lack of analytical tests for detecting B/SC in rendered product. AFIA shares this concern, and believes if and when FDA finalizes this rule, it should fund analytical method development. Although recordkeeping is an important tool, the development of a definitive, sensitive test for cattle B/SC will greatly assist in compliance efforts.

AFIA is aware the agency has developed an enhanced polymerase chain reaction (PCR) analytical test for bovine material in feed product. Of concern is the relative sensitivity of such a test that detects bovine protein that is airborne in or near feed milling operations. Before, FDA implements the regulatory testing of feed products, the agency needs to seriously consider the impact of airborne particles on the detection limits of this test method. AFIA does not support the use of such extremely sensitive methods that could result in positive findings for feed mills which do not handle prohibited mammalian protein in their manufacturing operations.

Additional Recordkeeping Should be Required Only for Rendering Operations

FDA asks for comments on extending recordkeeping requirements for this proposed regulation to industry segments beyond rendering operations. FDA explained the agency believes this would be redundant and therefore of little use. This proposed rule would require the removal of B/SC in certain cattle prior to rendering any tissue. The documentation (or testing, if developed) to insure this action has been taken must necessarily be done at the rendering operation. After the product is rendered, it would seem of little value to require records downstream from rendered product customers. Therefore, AFIA supports FDA's position that recordkeeping at the rendering operation should be required to document the removal of B/SC from applicable cattle, and no other operations should be required to maintain additional, new records.

FDA Should Compare Any Submitted, Relevant Comprehensive Economic Analysis Against FDA's Published Ones To Insure the Full Magnitude is Addressed

The economic impact of the proposed regulation on the rendering and animal production industries may be significant. AFIA believes the FDA should reevaluate the economic analysis of this rule prior to finalizing. Such an analysis should consider the overall economic impact of the proposed rule on all affected parties and be based on submitted, relevant data derived from a broad segment of the affected industries.

Finally, AFIA cannot stress strongly enough that this and future notices and rulemaking should be directed to animal health, as USDA and FDA have removed as many human health

concerns as are scientifically justified through previous actions banning the use of SRMs and downers in the food supply and related products.

In summary, AFIA generally supports FDA's proposed rule, but believes the proposal should be amended to allow in animal feed brains and spinal cords from dead and non-ambulatory cattle less than 30 month of age. FDA should pursue testing methodologies to detect B/SC in feed. The rendering industry should be required to keep additional records, and rendering industry customers should not have a duplicative recordkeeping burden. FDA and other federal agencies, in concert with state and industry interests, must address and develop practical and responsible alternatives and funding for disposal of additional carcasses and SRM material produced under this proposal.

AFIA appreciates the opportunity to offer these comments.

Sincerely,

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